UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE VIROPHARMA INCORPORATED SECURITIES LITIGATION	Civil Action No. 12-2714 CLASS ACTION

LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED CLASS ACTION COMPLAINT

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PRELIMINARY STATEMENT

In this classic case of securities fraud, Defendants, while in possession of nonpublic, material information from the Food and Drug Administration ("FDA"), made false and misleading statements to the market that directly contradicted what the FDA had told them.

In December 2011, after the FDA approved ViroPharma's supplemental New Drug Application ("sNDA") to revise the package labeling for Vancocin, Defendants told the market that ViroPharma met the qualifications for an additional three years of marketing exclusivity for Vancocin based on the approved sNDA and a new law that allowed for exclusivity if the applicant could show that the drug could be used for a new "condition of use." Defendants further told the market that they expected the FDA to agree with their position. This was an important announcement for the Company because ViroPharma had been waging (and losing) a six-year campaign to keep generic competition from entering the market and threatening its Vancocin monopoly. The exclusivity opportunity was the Company's best and only hope for keeping the monopoly alive.

Unbeknownst to investors, however, the FDA had already privately told Defendants ***on at least four occasions*** that the clinical study upon which ViroPharma based its exclusivity application—the Genzyme Study—was not an adequate and well-controlled trial as to Vancocin. This was significant because an adequate and well-controlled trial was a pre-requisite to establishing that Vancocin could be used to treat a new "condition of use" – a requirement admittedly known by Defendants and set out plainly in the governing statute.

In addition, in the letter approving ViroPharma's sNDA, the FDA told Defendants that Vancocin's label was ***not*** being approved for a "new indication" or a "new dosing regimen." Yet, days after receiving the Approval Letter, Defendants publicly stated in their application for exclusivity that the label did in fact approve a "new indication" and a "new dosing regimen," and that these new "conditions of use" could be used to support Vancocin's exclusivity bid. These statements were patently false given what the FDA had already told Defendants.

On April 9, 2012, the FDA denied ViroPharma's petition for exclusivity informing investors for the first time what was already known to Defendants--that the Genzyme Study had been inadequate to support a new condition of use for Vancocin, and Defendants knew their statements that Vancocin had a "new indication" and "new dosing regimen" were false based on certain language in the FDA Approval Letter. On the same day, the FDA also approved applications for three generic drug forms of Vancocin, abolishing Vancocin's monopoly. ViroPharma's stock dropped 22% on this news.

Calling this a case of "fraud by hindsight," Defendants try to divert the Court's attention by claiming that, as an issue of first impression, they could not have known how the FDA would ultimately interpret the term "condition of use." But, what Defendants ***could know and did know, because the FDA told them so,*** is that they never submitted "substantial evidence" based on an adequate and well-controlled trial—which was a required precursor to establishing a new "condition of use." This information was material to investors and Defendants had a duty to disclose the FDA communications.

Indeed, at a ***minimum***, regardless of whether the FDA would ultimately construe "condition of use" liberally (and allow Defendants exclusivity based on merely rewording their label), or conservatively (and require the drug to treat a new disease), Defendants would have had to submit an adequate and well-controlled trial in support of their exclusivity application. They did not, but represented to the market that they did.

Defendants' attempts to hide behind the Safe Harbor fail because many of Defendants' statements were statements of present fact, not protected by the Safe Harbor. And, even for those that may have arguably been considered forward looking, Defendants' cautionary language simply does not suffice. Defendants knew the risks they were warning of had already come to pass.

Defendants' truth on the market argument is likewise without merit. As Plaintiff's industry expert confirms, even if the FDA's letter to ViroPharma approving the sNDA was publicly available at the start of the Class Period, a lay person would not have understood the significance of the letter's statements regarding testing under PREA, particularly without the context of the prior communications by the FDA regarding the applicability of the Genzyme Study to ViroPharma's application. However, there is, at a minimum, a disputed question of fact as to whether that letter was ever publicly available. Defendants' legal challenges to scienter are equally deficient. Defendants can not deny that they knew about the FDA communications in question—quintessential evidence of scienter. Since Plaintiff has adequately pled a claim for securities fraud, Defendants' motion should be denied.

SUMMARY OF ALLEGATIONS

I. The Company and Its Core Drug - Vancocin

ViroPharma, Inc. ("ViroPharma" or the "Company"), is a biopharmaceutical company that develops, licenses, and markets pharmaceutical drugs. ¶ 2. Its most important drug was Vancocin, an antibiotic drug designed to treat a severe infection of the gastrointestinal tract called Clostridium *difficile* Associated Diarrhea ("CDAD"). *Id.* Because Vancocin was the only drug approved by the FDA to treat CDAD, ViroPharma enjoyed an extremely lucrative monopoly. *Id.*

Vancocin sales totaled nearly $1.5 billion between 2005 and 2011. ¶¶ 38-39. From 2005 through 2008, Vancocin accounted for ***100%*** of the Company's revenues. ¶ 38. Vancocin's success eventually allowed ViroPharma to grow and add other drugs to its product line, yet Vancocin continued to account for a substantial portion of the Company's sales. ¶ 39. In 2011 alone Vancocin net sales totaled over $280 million, representing over 50% of the Company's sales. *Id.* Because of its dominant market position, the Company spent very little marketing Vancocin, allowing ViroPharma to reap an incredible ***97% profit margin*** on Vancocin sales. ¶¶ 40-41.

II. New FDA Regulations Threaten ViroPharma's Vancocin Franchise

ViroPharma initially enjoyed an unchallenged monopoly for the treatment of CDAD because the barriers to entry for FDA approval of generic versions of Vancocin were extremely high. ¶¶ 46-49. Specifically, lengthy, expensive and ultimately cost prohibitive human clinical trials were required for a generic equivalent to Vancocin to be approved by the FDA. *Id.*[1]

Then in March 2006, the FDA changed the way generic drug manufacturers could prove that their drug was equivalent ("bioequivalent") to Vancocin. The FDA determined that bioequivalence could now be established through simple laboratory testing instead of testing in human subjects, thus substantially lowering the hurdle for generic competition to enter the market. ¶ 50. In a reflection of the importance of Vancocin to ViroPharma's business, ViroPharma's stock price was crushed by the announcement, triggering a multi-day sell-off which cut ViroPharma's market capitalization by 40% (approximately $500 million). ¶ 51. It was predicted at the time that the loss of marketing exclusivity would cause the Company to lose 60-90% of the Vancocin market within months. ¶ 43.

[1] The Drug Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Amendments" or "Hatch –Waxman") governs the submission and approval of generic competitors to drugs whose patents have expired. ¶ 45. 21 U.S.C. § 355 *et seq.*

III. ViroPharma's Desperate Efforts to Maintain Exclusive Marketing Rights for Vancocin

Facing the potential loss of its main revenue source, ViroPharma immediately challenged the legality of the FDA's decision through the filing of a Citizen's Petition with the FDA. ¶ 52. ViroPharma then proceeded to supplement and amend its Citizen's Petition ***twenty times*** from 2006 through 2011. ¶ 52. Since the FDA was required to consider and respond to ViroPharma's Citizen's Petition, and a generic competitor to Vancocin could not be approved until after the FDA issued a formal response (¶ 53), ViroPharma continued to enjoy marketing exclusivity for Vancocin while its supplemented and amended Citizen Petition was pending. However, Vancocin's future still remained uncertain as the FDA would ultimately have to issue a decision on its Citizen's Petition--a decision that potentially could grant generics an easy way into the market and jeopardize ViroPharma's monopoly on Vancocin sales.

IV. The New QI Act Provides Hope For Vancocin Exclusivity But Only If ViroPharma Could Establish a New Condition of Use Through Adequate and Well-Controlled Trials

In October 2008, Congress passed a new law, called the QI Act, which amended the Hatch-Waxman Amendments to allow for three additional years of marketing exclusivity for certain "Old Antibiotics"[2] provided that a drug manufacturer met certain requirements. ¶ 57. ViroPharma saw the passage of the QI Act, as an opportunity to try to extend its exclusivity for Vancocin.

With the good news of the passage of the QI Act came some bad news for ViroPharma when, in December 2008, the FDA issued draft guidance confirming its position that generic versions of Vancocin could prove their bioequivalence to Vancocin through only simple lab tests. ¶ 65. ViroPharma submitted comments objecting to the guidance in March 2009 to continue to forestall the FDA's ultimate decision on the issue. ¶ 66. However, the draft guidance was confirmed in August of 2009, when an FDA advisory committee voted unanimously in favor of permitting lab tests alone to establish bioequivalence. ¶ 66. Based on the new guidance, the QI Act represented ViroPharma's only chance of keeping generic competitors for Vancocin at bay. *Id.*

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[2] "Old Antibiotics" refers to antibiotics approved before the effective date of the Food and Drug Modernization Act of 1997.¶¶ 57-58. The FDA expressly cited Vancocin as an "Old Antibiotic." ¶ 58.

The QI Act provided for three additional years of marketing exclusivity in very limited circumstances. ¶ 60. The exclusivity period was only available for "Old Antibiotics" that were administered for a new "condition of use."[3] ¶ 60. 21 U.S.C. § 355(v) *et seq.* In other words, in order for an Old Antibiotic like Vancocin to be granted three additional years of marketing exclusivity, it had to be marketed for a new condition of use—one which had not previously been approved by the FDA. *Id.*

Defendants then concocted a two-step plan in an effort to gain three more years of exclusivity to market Vancocin. As a first step, ViroPharma licensed a failed clinical study from Genzyme (the "Genzyme Study"), in which Genzyme tested its own unapproved drug, tolevamer, on patients diagnosed with CDAD. ¶ 68. The Genzyme Study was designed to test whether tolevamer was as effective as Vancocin. *Id.* However, the Genzyme Study failed to show tolevamer's effectiveness, so Genzyme could not use the results to support a new drug application for tolevamer.

[3] As the legislative history of the QI Act reveals, the intent of providing an additional period of marketing exclusivity was to encourage the development of "novel uses" for "Old Antibiotics." ¶¶ 61-63. While "condition of use" was not specifically defined in the QI Act itself, Congress made clear that a new "condition of use" rose to the level of a "new indication." ¶ 61. Defendants would later claim that Vancocin's new label reflected a "new indication." ¶ 110.

ViroPharma, on the other hand, used the failed Genzyme Study to support a supplemental New Drug Application, or sNDA, for a new Vancocin label with an expanded description of the performance of Vancocin. As step two, and after the sNDA for the new label was approved, ViroPharma applied for three years of marketing exclusivity under the QI Act, arguing that the newly-approved label demonstrated a new dosing regimen, new indications, and other new "conditions of use" for Vancocin, sufficient to qualify for exclusivity. ¶ 67, 21 U.S.C. § 355(v)(3)(B).

The Federal Food Drug and Cosmetic Act ("FDCA") (of which Hatch-Waxman is a part of) makes it very clear, however, that any claim that a drug is effective to treat a new condition must be supported by "substantial evidence [from adequate and well-controlled investigations] that the drug will have the effect it purports or is represented to have under the ***conditions of use*** prescribed, recommended, or suggested in the proposed labeling thereof." ¶ 44. 21 U.S.C. § 355(d)(5) *et seq.* (emphasis added). While ViroPharma's application for exclusivity was the first one brought under the new QI Act, and while the FDA had not yet ruled on what kind of "condition of use" was covered under the QI Act, the FDA had established that at a minimum, "substantial evidence" based an adequate and well-controlled trial was required to qualify for exclusivity. *Id.* Defendants were well-aware of the "substantial evidence" requirement and made reference to it in their Citizen's Petition Supplement.[4]

V. The FDA Tells ViroPharma that the Genzyme Study Does Not Represent Adequate or Well-Controlled Trials as to Vancocin

A fatal flaw in ViroPharma's plan, however, was the fact that the Genzyme Study was specifically designed to test the effectiveness of tolevamer compared with that of Vancocin and

[4] *See* Citizen's Petition Supplement at 9, 21. The Citizen's Petition Supplement, signed by Defendant Doyle ,is attached hereto as Exhibit 1.

another antibiotic, metronidazole, in treating CDAD (the same indication that Vancocin was currently approved for treating). ¶ 68. The Genzyme Study was ***not*** designed ***in advance*** to test whether Vancocin was as effective, or more effective than a placebo (*i.e.*, better than receiving no drug at all). Thus, by design, the Genzyme Study could not be considered an adequate and well-controlled investigation ***as to Vancocin***.[5]

More importantly, ***and the crux of the case here***, is that Defendants were told privately by the FDA on at least four occasions prior to the start of the Class Period that the Genzyme Study upon which their exclusivity claim was based was not an adequate and well-controlled trial ***as to Vancocin*****.** While Defendants' attempt to gloss over the FDA's communications in their motion to dismiss (Def. Br. at 7-8), the information provided by the FDA is highly significant. Because of the Study's deficiencies, and pursuant to the FDA rules and regulations (which were admittedly known by Defendants), the Genzyme Study could not support a claim for a new indication, new dosing regimen or other new condition of use for Vancocin.

For example, in response to ViroPharma's sNDA application, the FDA communicated privately to Defendants on February 18, 2011 (¶¶ 75-77), May 20, 2011 (¶¶ 78-79), May 24, 2011 (¶ 80), and December 8, 2011 (¶¶ 81-85) that the Genzyme Study was not adequate and well-controlled as to Vancocin because: (1) the purpose of the study was not to test Vancocin's effectiveness,[6] and (2) Vancocin could not be "compared" to another drug based on the Study so there was no placebo or "control."[7] Because of these study deficiencies, the FDA determined on December 8, 2011, at a final labeling conference, that the new Vancocin label could only be considered "descriptive" in nature.

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[5] An "adequate and well-controlled trial" as used by the FDA, is clearly defined in 21 C.F.R. § 314.126. In order to meet the requirements of 21 C.F.R. § 314.126, a study or trial must have a "clear statements of the objectives of the investigation" designed to permit a valid comparison with a control, such as a placebo, to provide a quantitative assessment of the drug's effect. *Id.* ¶ 77.

[6] A study must have "a clear statements of the objective of the investigation." 21 C.F.R. § 314.126. A study that changes its primary hypothesis after the fact does not represent an adequate and well-controlled trial because such a post hoc change introduces the potential for statistical bias. ¶ 79; 21 C.F.R. § 314.126. The FDA called ViroPharma's use of the Genzyme Study "secondary analyses" in its February 18, 2011 letter. In its May 20, 2011 letter, the FDA said that this "secondary analysis" did not meet the definition for "an adequate and well-controlled investigation." (¶ 75-76, 78).

The FDA's message was unequivocal—while ViroPharma might have qualified for a new label for Vancocin, the Genzyme Study did not rise to the clear definition of an adequate and well-controlled trial as to Vancocin on many levels, which was a prerequisite for an additional period of exclusivity. This important information was never conveyed to the public by Defendants.

On December 14, 2011, the FDA granted ViroPharma's sNDA for the new label. The Approval Letter did not mention that Defendants were already repeatedly told privately by the FDA that the Genzyme Study did not meet the criteria for an adequate and well-controlled trial. The Letter did state that Defendants did not submit information regarding, or meet the requirements for, the Pediatric Research Equity Act ("PREA"), ¶ 88, which meant that the label was not being approved for a new indication or new dosing regimen (¶¶ 89, 93, 135). This is also significant, because Defendants would later claim publicly that ViroPharma was entitled to marketing exclusivity precisely because the approved sNDA label changes were for a new indication and a new dosing regimen. ¶ 93.

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[7] In the FDA's communications on February 18, 2011, the FDA called ViroPharma's attempt to "compare" Vancocin to metronidazole the "multiplicity of comparisons." ¶ 77. On May 20, 2011, the FDA stated that ViroPharma could not compare Vancocin to a placebo or control because the hypothesis (to compare Vancocin to another drug) was not the stated goal of the Genzyme Study. ¶ 78. ViroPharma agreed on May 20, 2011 that it would not be making "comparative claims" on the label. Def. Ex. 5. Defendants' admission is significant because a comparison to a placebo is a required component of an adequate and well-controlled trial 21 C.F.R. §314.126(b)(2)(i). The FDA reiterated this point on December 8, 2011, when the FDA told the Defendants that the label could not contain any comparative information. ¶ 81.

VI. Defendants' Class Period Statements on Their Exclusivity Application Fail to Reveal the Deficiencies of the Genzyme Study

Despite being told by the FDA in private communications that the Genzyme Study did not meet the criteria for adequate and well-controlled trials as to Vancocin (a prerequisite to show that a drug was effective for a new condition of use), Defendants nevertheless publicly stated their unsupported belief that Vancocin "meets the requirements" for exclusivity under the QI Act based on the Genzyme clinical data. ¶¶ 95, 110, 113, 118, 125, 128, 132. Defendants also made other comments on maintaining exclusivity and what that would mean for ViroPharma's revenues going forward (¶¶ 113, 118, 125, 132), yet failed to disclose what the FDA repeatedly told them. No matter which way the FDA interpreted "condition of use," there was simply no way that Vancocin could qualify for exclusivity based on the Genzyme Study.

On January 4, 2012, the Company published its Citizen's Petition Supplement which was the official request that the FDA grant exclusivity based on the newly approved sNDA. ¶¶ 107-112; Exhibit 1. Like Defendants' other Class Period statements, the Citizen's Petition Supplement represented that the Vancocin sNDA satisfied the requirements for exclusivity under the QI Act, including the requirement that the Company provide "substantial evidence" from adequate and well-controlled trials. ¶ 108; Exhibit 1 at 9, 21. The Citizen's Petition Supplement also referred to the label changes as "new conditions of use" without disclosing that the FDA already told ViroPharma that the Genzyme Study was not adequate and well-controlled as to Vancocin.

Most egregious and misleading, however, were Defendants' representations in the Citizen's Petition Supplement that the label changes reflected a "new indication and dosing regimen" for Vancocin. ¶ 109. These statements were blatantly false since the Approval Letter and prior communications had already informed Defendants that the new label could not support a new indication or new dosing regimen.

In the meantime, while keeping this information private, Defendants Doyle and Rowland sold their personal shares of ViroPharma stock for an aggregate total of over $8 million in profit over the short four month Class Period. ¶¶ 160-165. In addition, while the Company was waiting for the FDA to decide its baseless application for exclusivity, it was able to reap an additional $66 million from Vancocin sales, representing nearly half of the Company's net sales for the quarter. ¶ 154.

VII. The Truth Is Revealed

On April 9, 2012 after the market closed, the FDA responded to Defendants' Citizen's Petition, formally denying ViroPharma's request for exclusivity. ¶ 134. The FDA denial was based on the fact that ViroPharma's sNDA was not for a new "condition of use" as per the QI Act. Specifically, the FDA stated that ViroPharma's exclusivity premise was "inconsistent" with two things. First, it was "inconsistent with the contents of the sNDA that contained those studies." ¶ 135. Indeed, the FDA told the Company that the Genzyme Study on which the sNDA was based was not an adequate and well-controlled trial as to Vancocin and thus could not support a new condition of use. Second, ViroPharma's position was inconsistent with the Approval Letter, which noted Defendants' failure to include PREA assessments. *Id*. The FDA explained in detail that ViroPharma's failure to conduct an assessment under PREA meant that the Company ***knew*** it was not applying for a new indication or new dosing regimen. *Id.* In addition, the FDA reprimanded the Company for their monopolistic delay tactics and excessive submissions to the FDA. ¶ 136.

Once the market learned the truth, ViroPharma's stock price fell $6.17 per share or 22%, on April 10, 2012 from $28.61 to close at $22.44 on extraordinarily high volume. ¶ 147.

ViroPharma's stock price continued to drop through April 11, 2012 as the full impact of the news was absorbed by the market to close at $21.86 on continued high volume. *Id.*

ARGUMENT

I. Applicable Legal Standards

In ruling on a motion to dismiss, a court must view the facts alleged in the complaint in the light most favorable to the plaintiff, assume the truth of the allegations, and draw all reasonable inferences in plaintiff's favor. *See Maio v. Aetna, Inc*., 221 F.3d 472, 481-82 (3d Cir. 2000).[8] The purpose of a motion to dismiss is not to determine "whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *See In re Burlington Coat Factory Sec. Litig*., 114 F.3d 1410, 1420 (3d Cir. 1997). Consequently, "when a complaint adequately states a claim, it may not be dismissed based on a district court's assessment that the plaintiff will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the fact finder." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007) ("*Twombly*").

Accordingly, a complaint "attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," but rather need only provide the grounds of entitlement to relief and raise a right to relief above the speculative level. *Twombly*, 550 U.S. at 555. In other words, a complaint must simply "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A complaint adequately states a claim under § 10(b) by pleading that the Defendants (i) made a material misrepresentation or omission of information that it had a duty to disclose; (ii)

[8] Citations and internal quotations are omitted, and emphasis is added, unless otherwise noted.

with scienter, (iii) in connection with a purchase or sale of securities; (iv) upon which Plaintiffs relied; (v) proximately causing Plaintiffs to suffer injury.[9] 17 C.F.R. § 240.10b-5.

Accepting Plaintiff's allegations as true and drawing all reasonable inferences in its favor, the Court should deny Defendants' motion to dismiss.

II. The Complaint Adequately Alleges that Defendants Made Materially False or Misleading Statements and Omissions

A. The Complaint Pleads Misrepresentations of Fact with Required Specificity

A plaintiff in a securities fraud class action satisfies the Private Securities Litigation Reform Act of 1995 ("PSLRA" or "Reform Act") and Rule 9(b) of the Federal Rules of Civil Procedure by "specify[ing] each allegedly misleading statement, the reason or reasons why the statement is misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Institutional Investors Group v. Avaya, Inc*., 564 F.3d 242, 259 (3d Cir. 2009) ("*Avaya*") (citing 15 U.S.C. §78u-4(b)(1)). "Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of securities fraud with all of the essential factual background that would accompany 'the first paragraph of any newspaper story'-that is, the 'who, what, when, where and how' of the events at issue." *In re Suprema Specialties, Inc. Sec. Litig*., 438 F.3d 256, 276-77 (3d Cir. 2006).

Plaintiff has easily satisfied the PSLRA and Rule 9(b) here. In addition to identifying "what" the statement was, "who" made it and "when" and "where" it was made (¶¶ 95, 107, 113, 118, 125, 128, 131), Plaintiff has also pled "***why***" each statement was false or misleading. For example, as alleged in the Complaint, during the Class Period:

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[9] Defendants' motion challenges only whether Plaintiff has adequately alleged a false statement or omission and whether Plaintiff has adequately alleged scienter. Thus, any challenge on Reply to loss causation, reliance, or that the misstatements were made in connection with a purchase or sale of securities, should be ignored by the Court. *See Baker v. Pa. Econ. League, Inc. Ret. Income Plan*, 811 F. Supp. 2d 1136, (E.D. Pa. Aug. 23, 2011) (holding arguments may not be raised for the first time in a reply brief) (collecting cases).

- **Defendants stated their belief that Vancocin's label met the requirements for QI Act Exclusivity**. ¶¶ 95, 110, 113, 118, 125, 128, 132. The statements were false and misleading because Defendants omitted that the FDA told them the studies upon which Defendants based their new label did not ***and could not*** meet the QI Act standards for exclusivity. ¶¶ 75-90, 96 (b)-(e), 111 (c)-(e), 114 (b)-(e), 119 (b), (c), (e), 126, 133.

- **Defendants stated that under FDA regulations, labeling changes based on new clinical investigations may be entitled to three years of exclusivity.** ¶ 95, 118, 132. The statement was false and misleading because Defendants omitted that, as applied to "Old Antibiotics," FDA regulations stated that the changes had to reflect a new condition of use to qualify for exclusivity, required "adequate and well-controlled studies" in order to support a new condition of use, and the FDA had already told Defendants that the Genzyme Study was not "adequate and well controlled." ¶ 99, 120, 133.

- **Defendants stated that the label contained "new indications" and a new dosing regimen, and "numerous new conditions of use"** ¶ 110, Appendix A. The statements were false and misleading because they omitted that the FDA communicated to Defendants in the sNDA Approval Letter and other private communications that the label ***did not*** support a new indication or new dosing regimen and that the Genzyme Study ***could not*** support a new condition of use. ¶¶ 87, 111 (a)-(e).

- **Defendants stated that the new indication "was one of the new changes to the Vancocin labeling approved in the recent sNDA"** ¶ 110. The statements were false and misleading because the Approval Letter, received by Defendants, did not "approve" a new indication by approving the sNDA. ¶¶ 87, 111 (a)-(e).

- **Defendants stated that the new labeling information "derives from new controlled clinical data."** ¶ 110. The statements were false and misleading because Defendants omitted that the FDA told them that the Genzyme Study upon which the new label was based was not an adequate and well-controlled clinical trial as to Vancocin. ¶¶ 75-90.

- **Defendants stated that the label contained efficacy data for the BI/NAP1 strain of the disease.** ¶ 95. This statement was false and misleading because new efficacy for Vancocin against CDAD caused by the B1/NAP1 strain could only be shown through an adequate and well-controlled trial, and Defendants had been told that the Genzyme Study did not meet this standard. ¶ 98.

- **Defendants stated that based on the changes to the label, the Company expected to reap record sales on their exclusivity-protected Vancocin.** ¶¶ 113, 118, 125. The statements were false and misleading because the FDA told Defendants that the studies upon which Defendants based their new label did not ***and could not*** meet the QI Act standards for exclusivity. Therefore, there was no basis to make bullish projections for Vancocin. ¶¶ 115, 122, 126.

Indeed, Defendants do not contest that Plaintiff adequately particularizes the statements that are alleged to be false and misleading and explains in detail why the statements were false and misleading when made. Instead, Defendants claim that their statements are not actionable because they are protected by the PSLRA's Safe Harbor, and even if not protected by the Safe Harbor, Defendants had no duty to disclose the information described above that was provided to them by the FDA. As discussed herein, both of these arguments fail. In addition, Defendants proffer facts outside the Complaint and ask the Court to determine facts that are in dispute. Such tactics are improper on a motion to dismiss and the proffered facts should be ignored by the Court.

B. Defendants Had a Duty to Disclose Material Information Relating to Their Class Period Statements

"Rule 10b-5 impose[s] upon defendants the duty to disclose any material facts that are necessary to make disclosed material statements, whether mandatory or volunteered, not misleading." *In re Craftmatic Sec. Litig*, 890 F.2d 628, 641 (3d Cir. 1989). This "statutory duty to 'speak the ***full*** truth'" arises "when defendant undertakes to say anything [concerning the issue]." *Id.*; *see also Hoxworth v. Blinder, Robinson & Co.*, 903 F.2d 186, 200 n.19 (3d Cir. 1990) ("misleading half-truths," defined as "failures to disclose sufficient information to render statements actually made not misleading," are actionable under Rule 10b-5). A defendant is liable for an omission "where silence would make other statements misleading or false." *Wallace v. Sys. & Computer Tech. Corp.*, No. 95-cv-6303, 1997 WL 602808, at *9 (E.D. Pa. Sept. 23, 1997).

Generally, information is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988); *In re Aetna Inc. Sec. Litig*., 34 F. Supp. 2d 935, 945 (E.D. Pa. 1999) ("A statement or omission is material if there is a "substantial likelihood that, under all the circumstances, the [statement or omission] would have assumed actual significance in the deliberations of the reasonable shareholder."). Generally, issues of materiality are reserved for the jury to decide. *In re U.S. Interactive, Inc. Class Action Sec. Litig.*, No. 01-CV-522, 2002 WL 1971252, at *7 (E.D. Pa. Aug. 23, 2002) ("[Q]uestions of materiality have traditionally been viewed as particularly appropriate for the trier of fact.").

Where, as here, it is alleged that the company's stock traded on an "efficient market" (¶¶ 178, 182), "the Third Circuit has instructed courts to measure materiality 'post hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm's stock'." *In re Merck & Co., Inc. Vytorin/Zetia Sec. Litig*., CIV. A. No. 08-CV-2177 (DMC), 2009 WL 2855601, at *3 (D.N.J. Sept. 2, 2009); *In re Burlington Coat Factory Sec. Litig*., 114 F.3d 1410, 1425 (3d Cir. 1997) ("In the context of an 'efficient' market, the concept of materiality translates into information that alters the price of the firm's stock."). The Third Circuit maintains a "clear commitment" to the efficient market hypothesis. *Dutton v. Harris Stratex Networks, Inc*., 270 F.R.D. 171, 176-77 (D. Del. 2010) (citing *In re Merck & Co. Sec. Litig*., 432 F.3d 261, 269 (3rd Cir. 2005).

1. The Information Defendants Withheld From the Market Was Material

i. ViroPharma's Stock Price Movement Satisfies the Third Circuit's Materiality Test

As an initial matter, Defendants have failed to apply the correct standard to their materiality analysis. Def. Br. at 23. Defendants do not even mention the Third Circuit's "efficient market hypothesis" analysis for determining materiality, under which Plaintiff has clearly and adequately pled that Defendants' statements and omissions were material.

Specifically, Plaintiff alleges that Defendants misled the market by making false and/or materially incomplete statements concerning marketing exclusivity for Vancocin. When Defendants made these positive statements, ViroPharma's stock price jumped nearly 20%, and remained inflated throughout the Class Period. ¶ 100. Defendants failed to inform the market that their application for exclusivity was deficient; a fact known to Defendants because the FDA had told them so on five separate occasions prior to Defendant's making their false and misleading statements.[10] On April 9, 2012, after the market closed, the market learned that (1) Defendants knew the Genzyme Study was inadequate to support an exclusivity application, ***and*** (2) that Defendants' statements in their Citizen's Petition Supplement, including that Vancocin had a new "indication" and "new dosing regimen," were directly contradicted by the sNDA Approval Letter. ¶¶ 134-135.

As a result of the news, at the close of trading on April 10, 2012, ViroPharma shares declined 22% from the prior day's close. ¶ 147. *See Merck*, 2009 WL 2855601, at *3 (finding that plaintiffs adequately pled materiality where plaintiff alleged stock price declines of 12% and 15% when the truth was revealed to the market). As the court stated in *Merck*, "[a]ccordingly, because Plaintiffs adequately allege that [the company's] stock price experienced significant drops 'immediately following' disclosure of the [allegedly false or misleading information], the Court finds it "plausible on its face" that Defendants' misstatements and omissions relating thereto were indeed "material." *Id*. The Court should reach the same conclusion here.

[10] On February 18, 2011, (¶¶ 75-77), May 20, 2011 (¶¶ 78-79), May 24, 2011 (¶ 80), and December 8, 2011 (¶¶ 81-85) the FDA told Defendants that the Genzyme Study was not adequate and well-controlled as to Vancocin. On December 14, 2011, the FDA told Defendants that the label did not support a "new indication" or "new dosing regimen." ¶¶ 87-90.

ii. Even Under the Materiality Standard Advanced By Defendants, Plaintiff Has Adequately Pled Materiality

Even under the materiality standard Defendants advance, Plaintiff has alleged that the information that the FDA communicated to Defendants concerning Vancocin was material. Defendants' argument that "any materiality ascribed to any of the communications requires a hindsight application of the heightened standard that the FDA ultimately adopted—a standard that was not publicly known by ViroPharma or anyone else at the time," is simply not true.

Given that an adequate and well-controlled trial was a prerequisite for an application for a new "condition of use," and thus exclusivity, any communications from the FDA concerning the adequacy of the Genzyme Study would have been material to a ViroPharma investor. Indeed, the FDA told Defendants on at least four separate occasions that the Genzyme Study was not ***and could not*** be an adequate and well-controlled trial as to Vancocin. (February 18, 2011 ¶¶ 75-77, May 20, 2011 ¶¶ 78-79, May 24, 2011 ¶ 80, December 8, 2011 ¶¶ 81-86). This information was crucial to investors because if investors had known that the FDA did not consider the Genzyme Study an adequate and well-controlled trial as to Vancocin, they would not have believed Defendants' positive statements concerning Vancocin's exclusivity bid.

Defendants also claim that the issues in the FDA communications were resolved as reflected in the Approval Letter. This is also not true. The Approval Letter is wholly silent as to whether the Genzyme Study was an adequate and well-controlled trial as to Vancocin. While the new Vancocin label was approved, the approval did not remedy the inherent deficiencies in the Genzyme Study as it related to Vancocin.

Statements in the sNDA Approval Letter and Citizen Petition Supplement go hand in hand and were equally material to investors. Defendants were told in the Approval Letter that the label was ***not*** being approved for a "new indication" or "new dosing regimen" because

Defendants did not submit PREA data. Defendants then blatantly lied in the Citizen's Petition Supplement when they claimed that the sNDA label approved Vancocin's "new indication" and "new dosing regimen," (¶ 110) and called these changes "new conditions of use." *Id.*

Defendants misleadingly argue in their motion to dismiss that it is Plaintiff who attempts to conflate "a new indication" or "dosing regimen" with a "new condition of use." Def. Br. at 27. However, the plain language of Defendants' Citizen's Petition Supplement shows that Defendants represented to the public that a "new indication" and "new dosing regimen" represented a "new condition of use." Defendants made these representations knowing that the FDA did not agree that the label supported a "new indication[ ]" or "dos[ing] regimen." ¶ 88. The omitted information would clearly have been material to investors.

Defendants' final contention—that the FDA communications never mentioned the word "exclusivity"—is specious. The FDA did not need to use the word "exclusivity" to tell Defendants that the Genzyme Study was not adequate and well controlled as to Vancocin, and thus could not support a new condition of use. This standard was in the FDCA, and Defendants ***knew*** that to obtain exclusivity they would have to submit "substantial evidence" based on "adequate and well-controlled trials," as they referred to the standard in their Citizen's Petition Supplement. Defendants stated in support of their exclusivity application: "[t]he [Genzyme Study has] only been relied on by FDA 'to demonstrate substantial evidence of effectiveness' and safety of Vancocin, in the Vancocin sNDA," and "…substantial evidence of effectiveness [is] based on adequate and well-controlled studies as defined in § 314.126(b)…" Exhibit 1 at 9, 21.

2. Defendants Had a Duty to Disclose This Material Information

Defendants do not contest that they failed to inform the market of the FDA communications regarding the Genzyme Study. They argue instead that they had no duty to predict the FDA's decision. Defendants tried the same argument before and lost. In *In re Viropharma, Inc. Sec. Litig.*, No. CIV. A. 02-1627, 2003 WL 1824914 (E.D. Pa. Apr. 7, 2003), plaintiff alleged that defendants ViroPharma, Milano and others kept information from the market regarding Phase II trials for its drug Pleconaril. Those trials showed that Pleconaril might not be effective and were therefore relevant to whether this drug would be approved by the FDA. Like here, defendants argued they did not have a "duty to predict" what the FDA would do. The court, in finding that Defendants had a duty to disclose material information stated:

> The thrust of the Plaintiffs' Complaint, however, is not seeking to impose such a duty [to predict]. The Plaintiff is alleging that the Defendants breached their duty to not make material misstatements. Whether the Defendants had to predict the FDA's decision is irrelevant. They are liable under 10b–5 if they made statements that a reasonable investor would consider in deciding whether to buy stock. All investing is based on investors' perceptions about the future. The Plaintiffs in this case bought Viropharma securities based on their perception of whether Pleconaril would be approved by the FDA. Viropharma would not be responsible if its investors' perceptions were based solely on the company's predictions about the prospects for FDA approval. That is not the case, however. Rather the allegations in this case are that Viropharma made misstatements of fact which formed the basis for its investors' perceptions… Accuracy in these types of factual statements lies at the heart of what the securities laws are trying to protect.

Id. at *5 (citations omitted). The Court should reach the same conclusion here.

Defendants' other arguments are also without merit. Defendants claim they had no duty to disclose their "ongoing dialogue" with the FDA and rely on *In re MedImmune, Inc. Securities Litigation*, 873 F. Supp 953, 966 (D.Md.1995), to support their proposition. First, that Defendants engaged in a "dialogue" with the FDA does not protect their discussions from disclosure. *In re Amylin Pharms., Inc., Sec. Litig.*, No. 01CV1455BTM(NLS), 2002 WL 31520051, at *4, *6 (S.D. Cal. Oct. 10, 2002) (upholding misstatements and omissions despite claim that "FDA's suggestions were part of a 'continuous dialogue'"). Second, the *MedImmune* court opined that Defendants did not have a duty to disclose FDA's ***questions*** to the public and is thus distinguishable. *Id.* Here, Plaintiff is not alleging that Defendants failed to tell the market about the FDA's questions regarding the Genzyme Study, but rather, failed to tell the market about the FDA's ***decision*** that the Genzyme Study was not adequate or well-controlled as to Vancocin. Moreover, *MedImmune* actually supports Plaintiff's position. There, the court found actionable Defendants' positive statements about drug approval, where then FDA had privately communicated concerns to the company about problems with a study that would affect approval. *Id*. at 968. *See also In re Transkaryotic Therapies, Inc. Sec. Litig*., 319 F. Supp. 2d 152, 160 (D. Mass. May 26, 2004) ("The existence of a subjective scientific disagreement over the efficacy of Replagal should have been made known to investors, particularly where the FDA comprised the side that strenuously contested the drug's effectiveness."). Defendants' other cases cited to support their position (Def. Br. at 26) are inapposite because they rely on the premise that Defendants could not predict what the FDA would ultimately do with their exclusivity application—an argument that fails here.

Given that Defendants chose to speak on the issue of exclusivity (and spoke extensively thereon), they had a corresponding duty to reveal the material information regarding the FDA's conclusion on the Genzyme Study, precisely because the Genzyme Study was essential to exclusivity. *See also In re Merck & Co., Inc. Sec., Derivative & Erisa Litig*., MDL 1658 SRC, 2012 WL 3779309, at *3-4 (D.N.J. Aug. 29, 2012) (finding actionable omissions where company made statements regarding drug's safety but omitted known material facts undermining the assertion of overall safety profile).

3. There Was No Truth on the Market

Defendants next try to inappropriately advance a truth on the market defense to escape liability. Def. Br. at 23-25. They do so by relying on three documents not cited in or relied upon in the Complaint.[11] These documents—(1) Exhibit 7, which consists of an affidavit attaching a letter from the FDA FOIA office, and (2) Exhibits 16 and 17 which are two analyst reports—are not properly subject to judicial notice and cannot support a truth on the market defense.

Fed. R. Evid. 201(b) permits a district court to take judicial notice of facts that are "not subject to reasonable dispute in that [they are] either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002). Fed. R. Evid. 201(b)(2); *In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 390-91 (D.N.J. 2010) ("judicial notice applies [only] to self-evident truths that no reasonable person could question, truisms that approach platitudes or banalities"). *See also In re Astea Int'l Inc. Sec. Litig.*, CIV. A. 06-1467, 2007 WL 2306586, at *8 (E.D. Pa. Aug. 9, 2007).

Relying on a letter from the FDA FOIA office, Defendants request that the Court take judicial notice of the fact that the Approval Letter was published on the FDA website on December 15, 2011. However, the FDA FOIA letter does not state with certainty or as a "self – evident truth" that the Approval Letter was publically available on that date. Instead, the letter states "***[t]o the best of our knowledge***, the initial date of public accessibility is December 15, 2011." (emphasis added). Ex. 7-B. In addition, Defendants do not provide an authenticated screenshot of the FDA website from December 15, 2011 evidencing the Approval Letter's publication on that date.[12] Thus, because the FDA FOIA letter does not provide a fact that is

[11] *See In re Res. Am. Sec. Litig.*, No. CIV. 98-5446, 2000 WL 1053861, at *5 (E.D. Pa. July 26, 2000) ("To prevail on a 'truth on the market' defense at this stage of the litigation…defendants must establish that defense as a matter of law ***on the basis of the allegations of the Amended Complaint***…") (emphasis added).

[12] Defendants request only that the court take judicial notice of "documents produced in response to a Freedom of Information Act request" (Def. Br. at 9 n.5) referring to the FOIA letter from the FDA at Ex. 7-B, and do not specifically request that the court take judicial notice of the website appended as Ex. 7-C. This website purports to show publication of the "Approval Letter with an "Action Date" of 12/14/2011. According to the Forgues Affidavit, this website was accessed on December 7, 2012. This screenshot is irrelevant and should not be considered by the

continued…

"capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned," it does not rise to the level of judicial notice.

Moreover, whether the letter was readily available to the public during the Class Period is an issue in dispute. *See* Declaration of Carol C. Villegas in Support of Plaintiff's Opposition to Defendants' Motion to Dismiss, attached hereto as Ex. 2. Finally, even if the Court takes judicial notice of the FDA FOIA letter, the Court may not consider the letter for "the truth of the matter asserted therein." *See Viropharma*, 2003 WL 1824914, at *1 ("If a court adopted the approach of considering such documents for the truth of the matter asserted therein, it would be authorizing a trial by public documents, and thus imprudently expanding the scope of 12(b)(6) motions").

In submitting this letter, Defendants are asking to the Court to do just that; consider the letter for the truth of the matter asserted therein. Defendants argue that because the market was aware of the contents of the Approval Letter during the Class Period, Plaintiff cannot sustain its theory of fraud. Def. Br. at 9. However, Defendants' truth on the market defense fails for two reasons. First, "[t]he truth on- the-market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a §10(b) complaint for failure to plead materiality." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2000). "Before the truth on the market defense can be applied, the defendants must prove that the information that was allegedly withheld or misrepresented was 'transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by defendant's statements.'" *Res. Am.*, 2000 WL 1053861, at *4. Defendants simply can not meet the high burden required

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…continued
Court because it does not speak to the issue of whether the Approval Letter was actually available on the FDA website on December 15, 2011 and/or during the Class Period.

by this defense. Moreover, Defendants' public statements undercut their argument. Specifically, Defendants submitted confounding information to the market when, in contradiction of the Approval Letter, they stated in their Citizen's Petition that the sNDA supported a new indication and new dosing regimen. *See In re Merck & Co., Inc. Sec., Derivative, & ERISA Litig.*, MDL 1658 SRC, 2011 WL 3444199, at *35 (D.N.J. Aug. 8, 2011) (finding no "truth on the market" where defendants reassured the market their drug was safe, despite public information that it was not, because the information did not enter the market "with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information created by" the alleged misstatements).

Second, even if the Approval Letter was public and accessible, Defendants would have to show that the market understood the letter's implications. *Res. Am.*, 2000 WL 1053861, at *4 ("if it would take a financial analyst to make sense of a defendant's disclosures, then the disclosure cannot immunize them from liability"). According to Plaintiff's industry expert, Dr. David B. Ross, M.D., Ph.D., who was responsible for regulatory oversight of Vancocin at the FDA from 1996-2004, the implications of the Approval Letter to ViroPharma's request for exclusivity would not be understood by a lay person. *See* Declaration of Dr. David B. Ross in Support of Plaintiff's Opposition to Defendants' Motion to Dismiss, attached hereto as Ex. 3 ("Ross Decl.") ¶¶ 15-16, 18.[13] Moreover, the Approval Letter did not mention that the Genzyme Study was not an adequate and well-controlled study as to Vancocin —the very information Plaintiff alleges was concealed from the market. Ross Decl. ¶¶ 12, 15. A lay person would not have understood the significance of the letter's statements as they related to exclusivity, particularly without the context of the prior communications by the FDA. *See* Ross Decl. ¶¶ 15-16, 18. Thus, the letter can not support a truth on the market defense.

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[13] The information contained in the Approval Letter is nothing like the publicly available, generally known information that was the subject of Defendants' cited authorities in support of their truth on the market defense. Def. Br. at 24, citing *Klein v. Gen. Nutrition Cos.*, 186 F.3d 338, 343 (3d Cir. 1999) (no duty to disclose worldwide shortage of vitamin E); *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2007 WL 789432, at *3 (E.D. Pa. Mar. 15, 2007) ("*Discovery Labs. II*") (no duty to disclose "tutorial" on the Code of Federal Regulations).

Defendants also argue that market knew that Vancocin's exclusivity might not be granted based on the two analyst reports they request the Court take judicial notice of. First, the analyst reports are not referenced in the Complaint. Because they are beyond the scope of the Complaint, the Court should deny judicial notice. *Astea*, 2007 WL 2306586, at *8 (denying judicial notice where plaintiffs claims are not based on the documents).[14] Even if the Court takes judicial notice of the reports, the "opinions of analysts or reporters cannot be noticed for the truth of the matter stated therein." *In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 390-91 (D.N.J. 2010).

In addition, the analyst reports can not support a truth on the market defense at this stage of the litigation. Defendants submit these reports to show that the market was ***not misled*** by the Company's statements (Def. Br. at 11-12). Plaintiff, however, cites to numerous other analyst reports in the Complaint to show that the market was ***in fact misled***. *See i.e.*, ¶¶ 101, 103, 105, 116, 143. Even if the Court were to consider the reports, there is at least an issue of fact as to whether the alleged disclosures Defendants point to were conveyed with sufficient intensity and credibility to counter the false impression created by Defendants' misrepresentations. *See In re MBIA, Inc., Sec. Litig.*, 700 F. Supp. 2d 566, 583-84 (S.D.N.Y. 2010) ("Faced with these conflicting [analyst] reports, the Court cannot decide the fact intensive issue of truth-on-the-market on a motion to dismiss."); *Cf. In re Rent-Way Sec. Litig.*, 209 F. Supp. 2d 493, 498 (W.D.

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[14] *See also City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, No. 5:11-CV-04003-LHK, 2012 WL 3010992 (N.D. Cal. July 23, 2012); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. CIVA-04CV-1030-RPM, 2005 WL 4161977 (D. Colo. Oct. 20, 2005).

Pa. 2002). Finally, the surprised reaction of analysts when the truth became known further undercuts the supposed effectiveness of Defendants' purported disclosures. *See e.g.* ¶ 141 ("We believe investors had largely taken VPHM's word that the additional exclusivity would be granted…"). More importantly, the market reacted to the disclosures of the truth by sending the Company's stock price down 22%. ¶ 147. *Res. Am.*, 2000 WL 1053861, at *5 ("Such a drop in [stock] price creates a reasonable inference that the information [disclosed at the end of the Class Period] had not been previously available to the market"). Accordingly, Defendants' truth on the market defense should fail.

C. Defendants' False and Misleading Statements Are Not Protected By the Safe Harbor

Opinions, predictions, and other forward-looking statements are actionable if the speaker does not genuinely and reasonably believe them when they are made. *See In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 368 (3d Cir. 1993). The PSLRA only provides a safe harbor for forward-looking statements which are identified as such and are accompanied by a meaningful cautionary statement detailing important factors which could result in actual results differing materially from those statements presented. *See* 15 U.S.C. § 78u-5(c)(1)(A).

The Safe Harbor is unavailable to Defendants here because (1) several of Defendants' statements were not forward-looking; (2) for those statements that may be deemed forward-looking, the statements were not accompanied by meaningful cautionary language; (3) Defendants had actual knowledge that their statements were false and misleading and cannot, therefore, use the Safe Harbor as a shield to avoid liability.

1. Several of Defendants' Statements Were Not Forward Looking

i. Statements of Present Fact Are Not Protected By the Safe Harbor

Defendants erroneously identify various statements as forward-looking, Def. Br. at 17-22, and wholly ignore categories of statements of present fact. For example, Defendants claim that the Citizen's Petition Supplement "is self–evidently forward looking" (Def. Br. at 22). However, this is belied by the actual language used by Defendants in the Citizen's Petition Supplement. For example, Defendants stated: "[Vancocin's] indication itself ***was*** changed based on the new data and ***now*** includes a new recommended dose…" (¶ 110); "Vancocin's labeling ***was*** fundamentally and extensively changed in the new sNDA with numerous new condition of use." (*id.*); "Vancocin's previous C. difficile indication ***was*** changed based on these new studies." (*id.*); Vancocin's CDAD indication, however, ***was*** one of the new changes to the Vancocin labeling approved in the recent sNDA, such that it ***is*** protected by Vancocin's new 3 year exclusivity" (*id.*). These statements, as well as those detailed in Appendix A, are statements of present or historical fact as indicated by the verbs "was" and "is" and by use of the word "now," and therefore are not protected by the Safe Harbor. *See Local 731 I.B. of T. Excavators & Pavers Pension Trust Fund v. Swanson*, No. 09-799, 2011 WL 2444675 (D. Del. June 14, 2011).

Defendant's corresponding claim that the Citizen's Petition Supplement can not give rise to liability because it is a "request for future action" which contains "legal advocacy" is mistaken. (Def. Br. at 21-22). Courts, including in this District, have concluded that a claim of fraud may be premised on statements contained in a citizen's petitions filed with the FDA. *See, e.g., In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 536 n.8 (E.D. Pa. 2010) (statements contained in a citizen's petition submitted to the FDA may form the basis for fraud claim). *In re DDAVP Indirect Purchaser Antitrust Litig.*, No. 05-CV-2237 2012 WL 4932158, at *17

(S.D.N.Y. Oct. 17, 2012) (upholding fraud claim arising from statements contained in a citizen petition submitted to the FDA).[15]

Assuming, *arguendo*, that any of the statements contained in the Citizen's Petition supplement are considered forward looking, the Citizen's Petition Supplement is never identified by Defendants as a forward looking statement, as required by the PSLRA. Therefore, ***none*** of the statements in the Citizen's Petition can be protected by the Safe Harbor.

In addition, Defendants argue that the following statement is forward looking: "[t]hough the sNDA approval, Vancocin's label for the first time ***includes*** clinical safety and efficacy data for Vancocin in treating circulating strains of Clostridium difficile, including the BI/NAP1 strain." Again, Defendants' own language betrays their argument; this is a statement of present fact because it describes what the label ***currently*** contains. Statements about present or historical facts are by definition ***not*** forward looking, and thus are not protected by the Safe Harbor. *See Local 731 I.B. of T. Excavators & Pavers Pension Trust Fund*, 2011 WL 2444675. *See also* statements of present or historical fact identified in Complaint, ¶ 184 (a)-(h).

Finally, prefacing statements with the word "believes" does not automatically bring the statements within the PLSRA Safe Harbor. *In re Merck & Co., Inc. Sec., Derivative, & ERISA Litig.*, MDL 1658 SRC, 2011 WL 3444199, at *20 (D.N.J. Aug. 8, 2011) (finding defendants' "statement of belief" is not a forward-looking statement; "If anything, when the statement was made by Merck, it purported to be a representation of present fact-what Defendants believed at the time was the likely explanation for the VIGOR results."). This is because "statements about

[15] *GlaxoSmithKline*, cited by Defendants, does not stand for the proposition that a "legal position" cannot form a basis for fraud. Def. Br. at 22, citing *In re Glaxo SmithKline plc Sec. Litig.*, No. 05 Civ. 3751(LAP), 2006 WL 2871968, at *10 (S.D.N.Y. Oct. 6, 2006). There the court found the particular statements the company made "about the legal positions the company was taking with respect to patent protection" were forward-looking and that "there is simply nothing in the SAC that alleges that GSK misrepresented the legal positions it was taking." *Id.* In this case, the Complaint alleges the statements in the Citizen Petition Supplement did misrepresent the state of affairs and did omit material information received from the FDA.

present or historical facts, whose accuracy ***can*** be determined at the time they were made, are not forward-looking statements falling within the PSLRA's safe harbor." *In re Vivendi Universal, S.A. Sec. Litig.*, 765 F. Supp. 2d 512, 569 (S.D.N.Y. 2011). Defendants' statements concerning the approval of exclusivity were not forward looking because they were statements whose accuracy could be determined at the time they were made; the FDA had already privately opined that the Genzyme Study did not meet one of the exclusivity requirements. *See e.g., Transkaryotic*, 319 F. Supp. 2d at 161-62 (finding statements including "'[w]e believe that the totality of our renal and cardiac data is compelling and we believe that Replagal can be approved on this data'" were not forward-looking as "[t]hey are statements of present belief that are material and are conceivably in direct contradiction to known facts about the FDA's position"). *In re Amylin Pharms. Sec. Litig.*, No. 01CV1455, 2002 WL 31520051, at *8 n.3 (S.D. Cal., May 1, 2003) ("If a defendant states that it believes or expects that the FDA will approve its drug but has information tending to seriously undermine the accuracy of its statement, the statement is actionable.").

ii. Omissions of Present Fact Are Not Protected By the Safe Harbor

The protections of the "bespeaks caution" doctrine and the PSLRA's safe harbor only protect statements that are truly forward-looking. *Marsden v. Select Med. Corp.*, No. CIV. A. 04-4020, 2006 WL 891445, at *7 (E.D. Pa. Apr. 6, 2006) *vacated in part on other grounds*, 2007 WL 518556 (E.D. Pa. Feb. 12, 2007). These protections ***do not apply*** to statements challenged on the basis that they omitted 'present facts'--facts known at the time the statement was made. *Id; In re Cell Pathways Inc. Sec. Litig.*, No. 99-725, 2000 WL 805221, at *10-11 June 20, 2000). *In re Majesco Sec. Litig.*, No. CIV. A 05CV-3557 PGS, 2006 WL 2846281, at *4 (D.N.J. Sept. 29, 2006) "[a]llegations based upon omissions of existing facts or circumstances do not constitute forward looking statements protected by the safe harbor of the Securities Act." *See also Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, No. 00-4285 2002 WL 33934282, at *11 (D.N.J. June 26, 2002) ("Chubb") ("purposeful omissions of existing facts or circumstances do not qualify as forward-looking statements and are not protected by the safe harbor of the Reform Act."),

Cell Pathways is instructive and analogous. In *Cell Pathways*, the defendants made positive statements regarding their anticipated FDA New Drug Application ("NDA") approval based on their clinical trials. Unbeknownst to the public (but known by defendants), the clinical trials were flawed and could never support a successful application for the new drug. Defendants sought dismissal of plaintiff's claims arguing that each of the challenged statements regarding the company's plans and expectations for the NDA filing of their new drug were forward-looking because the statements related to the Company's future plans and used "language of futurity." *Id.* at 11. The plaintiffs challenged these statements arguing that the defendants made material omissions of existing facts, *i.e.*, they failed to disclose flaws in the Phase III trial for their new drug which meant they knew the FDA would not approve the drug. The court found that "allegations based upon omissions of existing facts or circumstances do not constitute forward looking statements protected by the safe harbor of the Securities Act." *Id.* *See also Marsden*, 2006 WL 891445, at *7 (holding Safe Harbor does not apply because "Plaintiffs challenge these statements on the basis that Defendants withheld present information").

Similarly, Defendants here claim that all of their statements regarding their "belief" that "Vancocin meets the requirement for exclusivity"(¶¶ 95, 110, 113, 118, 125, 128, 132) and their bullish projections based on the exclusivity approval (¶¶ 113, 118, 125) are forward looking and protected by the Safe Harbor. Def. Br. at 17-21. However, Plaintiff alleges that these statements were false and misleading when made because they omitted material information—that the FDA repeatedly told ViroPharma that the Genzyme Study was not an adequate and well-controlled trial as to Vancocin. Because Plaintiff's claims as to those statements are based upon omissions of existing fact, they do not fall within the Safe Harbor. *See e.g., In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998) (Statement that "[MobileMedia] ***believes*** the MobileComm acquisition will enhance it[s] competitive position" is misleading on the basis of omissions of facts known to MobileMedia at the time the statement was made…The safe harbor of the Securities Act does not insulate Defendants from liability for these omissions.").

2. The Purported Cautionary Language Was Neither Meaningful Nor Adequate

Even if any of Defendants' misstatements could be considered forward looking, Defendants' cautionary language was not sufficiently meaningful or adequate to satisfy the Safe Harbor.

First, as described above, the statements in the Citizen's Petition Supplement were (1) never identified by Defendants as forward looking, and (2) contain statements of present or historical fact. But, even assuming that the Citizen's Petition Supplement did not fail the test for the Safe Harbor on both these premises (which it does), Defendants concede that the Citizen's Petition Supplement does not contain any cautionary language. Def. Br. at 22 n.10. Based on Defendants' own admission, the Court need not look further—the statements in the Citizen's Petition Supplement are simply not protected by the Safe Harbor.

Second, Defendants failed to include the cautionary language required by the Reform Act for the oral statements made at the J.P. Morgan Global Health Conference on January 11, 2012. ¶ 118. The Reform Act imposes an additional burden on "oral" forward looking statements, requiring defendants to include a cautionary statement that the particular oral statement is a forward-looking statement, and that "actual results [might] differ materially from those [projected] in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i)-(ii). Defendants failed to both identify the statements as forward looking and failed to include language required by the Reform Act. *See* Def. Ex. 11; ¶¶ 123, 185 (a).[16] *See In re Honeywell Int'l, Inc. Sec. Litig.*, 182 F. Supp. 2d 414, 427 (D.N.J. 2002) (finding oral statement that was not "*particularly*" identified as forward looking and that failed to identify important factors "that could cause actual results to differ materially from those in the forward-looking statement" was not protected by the Safe Harbor). Thus, the statements made on January 11, 2012 by Defendants concerning Vancocin's exclusivity, and financial guidance related thereto, are not protected by the Safe Harbor.

Third, the language Defendants identify as purportedly cautionary was meaningless because Defendants knew that the pertinent risks ***had already materialized*** during the Class Period. Defendants warned: "There can be no assurance that: the FDA will confirm our belief that Vancocin meets the requirements for, and thus has received, three years of exclusivity…" (Def. Br. at 18; Dec. 14, 2011 Press Release and January 5, 2012 Press Release; February 28, 2012 Press Release and Earnings Call); "[T]he FDA may not agree with our belief that Vancocin meets the requirements for three years of exclusivity, which could result in significant competition from generic products and lead to a significant reduction in sales of Vancocin." (Def. Br. at 20; Feb 28, 2012 Form 10-K). However, Defendants already knew, because the FDA had already told them, that the sNDA did not satisfy one of the conditions necessary for exclusivity. In any event, assessing the cautionary language relied on by Defendants raises

[16] Moreover, Defendants fail an additional requirement for oral forward-looking statements which requires Defendants to identify "the document, or portion thereof, that contains the additional information about those [risk] factors relating to the forward-looking statement." 15 U.S.C. § 78u-5(c)(2)(B)(ii).

issues of fact and thus cannot provide the grounds for a Rule 12(b)(6) dismissal. *See In re Lucent Techs., Inc. Sec. Litig.*, 217 F. Supp. 2d 529, 557 (D.N.J. 2002) ("whether any cautionary language is sufficiently 'meaningful' raises fact issues that are improperly resolved on [a] motion to dismiss.").

3. Defendants Made Statements With Actual Knowledge That They Were False and Misleading

Finally, the PSLRA's safe harbor provision does not protect statements that were knowingly false when made. *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 536 (3d Cir. 1999). In other words, "the safe harbor provision does not afford corporations a free pass to lie to investors." *Chubb*, 2002 WL 33934282, at *11; *In re Vicuron Pharms., Inc. Sec. Litig.*, No. CIV. A. 04-2627, 2005 WL 2989674 (E.D. Pa. July 1, 2005). For example, in *Vicuron*, the Court found that because "[D]efendants allegedly had no basis to believe that FDA approval would occur, as they ***were aware*** of the shortcomings of anidulafungin…the following [statement] cannot fall under the safe harbor for forward-looking statements…: 'We successfully presented positive Phase III data for esophageal candidiasis; we filed the NDA on time in April.... And the timeline has FDA approval in a PDUFA date of February 25th of 2004 and product launch in Q2 of next year.'" *See also In re Interpool, Inc. Sec. Litig.*, No. 04-321 2005 WL 2000237, at *13 (D.N.J. Aug. 17, 2005).[17] Even if the Court finds Defendants' cautionary language to be adequate for some statements, those statements would still not be protected under

[17] Defendants argue that allegations a misrepresentation was made knowingly will not defeat the Safe Harbor. Def. Br. at 14-15. Contrary to their representations, there is no hard and fast rule in the Third Circuit. "There is still uncertainty [in the Third Circuit] as to whether a forward-looking statement protected by the PSLRA safe harbor for immateriality or cautionary statements is protected if plaintiff pleads that defendants had actual knowledge of falsity." *In re Aetna, Inc. Sec. Litig.*, No. CIV. A. 07-4451, 2009 WL 1619636 (E.D. Pa. June 9, 2009), *aff'd in part*, 617 F.3d 272 (3d Cir. 2010) citing *Avaya*, 564 F.3d 242, 2009 WL 1151943, at * 12. The more well-reasoned approach that Plaintiff here advances is a common sense approach: Defendants should not be given a license to lie. *Merck*, 2011 WL 3444199, at *20 ("The cases dealing with the scienter standard imposed by the safe harbor provision lend no support to Merck's position that only the stricter 'knowing falsity' standard will suffice in this case.")

the Safe Harbor because Defendants knew the statements were false when they made them. *See also* § II. *infra*. "No manner of cautionary language can cure false statements knowingly made." *In re Veritas Software Corp. Sec. Litig.*, No. 04-831-SLR, 2006 WL 1431209, at *7 (D. Del. May 23, 2006); *Aetna*, 34 F. Supp. 2d at 946 ("The "bespeaks caution" doctrine does not apply to presently known facts.").

III. The Complaint Establishes the Requisite Scienter

A. Applicable Standards

A plaintiff states a claim under §10(b) and Rule 10b-5, by alleging facts providing a strong inference that the defendants acted with scienter, *i.e.*, a mental state embracing intent to deceive, manipulate or defraud. *See In re RAIT Fin. Trust Sec. Litig.*, No 2:07-cv-03148-LDD, 2008 WL 378164, at *11 (E.D. Pa. Dec. 22, 2008). "This scienter standard requires plaintiffs to allege facts giving rise to a strong inference of either reckless or conscious behavior." *Avaya*, 564 F.3d at 267 (3d Cir.2009). Scienter may also be pled by alleging facts that establish motive and opportunity. *Advanta*, 180 F.3d at 534-35.

In determining whether a strong inference of scienter has been alleged, a court must: (1) "accept all factual allegations in the complaint as true"; (2) "consider the complaint in its entirety"; and (3) "take into account plausible opposing inference[s]." *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007). However, "[t]he inference that the defendant acted with scienter need not be irrefutable. . . or even the most plausible of competing inferences." *Id.* at 324. It must merely be "*at least as likely* as any plausible opposing inference," *Id.* at 328 (emphasis in original). Thus, a thus a tie is sufficient to avoid dismissal. *Id.*

Indeed, a court must consider "'whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 251 (5th Cir. 2009) (quoting *Tellabs*, 551 U.S. at 323 (emphasis in original)); *see also Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 351 (3d Cir. 2009) (finding scienter after examining the complaint "as a whole"). The analysis must be "case specific" and should "ultimately rest not on the presence or absence of certain types of allegations but on a practical judgment about whether, accepting the whole factual picture painted by the Complaint, it is at least as likely as not that defendants acted with scienter." *Avaya*, 564 F.3d at 269.

B. Defendants' Communications with the FDA Provide Conclusive Evidence of Scienter

"To adequately plead scienter, it is sufficient for plaintiffs to allege that defendants had knowledge of facts or access to information that contradicts their statements." *In re Cambrex Corp. Sec. Litig.*, No. 03-CV-4896(WJM), 2005 WL 2840336, at *11 (D.N.J. Oct. 27, 2005). Defendants were clearly in possession of information that undercut their public statements that Vancocin qualified for three more years of marketing exclusivity. Defendants ***knew*** they had to show "substantial evidence" through adequate and well-controlled studies to satisfy the requirements for exclusivity because they cited to this standard at least twice in their Citizen's Petition Supplement. Ex. 1 at 9, 21. Defendants also ***knew*** that the FDA did not consider the Genzyme Study—the basis for their exclusivity claim—to be an adequate and well-controlled study as to Vancocin. *Id.*[18] Moreover, the Approval Letter clearly stated that the label was not being approved for a new indication or dosing regimen, directly at odds with Defendants' public statements in their Citizen Petition Supplement that the label represented "new indications" a

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[18] Defendants do not deny that they were in receipt of the Approval Letter and participated in the alleged communications with the FDA regarding the deficiencies of Vancocin's sNDA. ¶¶ 151, 152, 157-159. Def. Br at 7-9. Nor do they dispute that these FDA communications told Defendants that the Genzyme Study—the basis for their exclusivity claim—was not an adequate and well-controlled study. *Id.*

"new dosing regimen" and "numerous new conditions of use." "[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002); *see also BancaCremi, S .A. v. Alex Brown & Sons, Inc.*, 132 F.3d 1017, 1037 n. 26 (4th Cir. 1997) ("Scienter exists 'if the defendant knew the statement was misleading or knew of the existence of facts which, if disclosed, would have shown it to be misleading.'"); *Monk v. Johnson & Johnson*, CIV. A. No. 10-4841 FLW, 2011 WL 6339824, at *8 (D.N.J. Dec. 19, 2011), *reconsideration denied*, 2012 WL 1884037 (D.N.J. May 22, 2012).

C. Vancocin was a Core Drug for the Company Providing Evidence of Scienter

The law is clear that knowledge of problems affecting the "core business" of a company is imputable to its officers where sufficient facts are alleged to give rise to an inference that they knew or should have known about the problems. *See, e.g., Avaya*, 564 F.3d at 271 ("The perceived importance of margins supports an inference that [the CFO] was paying close attention to these numbers."); *In re Aetna Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 953 (E.D. Pa. 1999); *Aviva Partners LLC v. Exide Techs.*, No. 05-3098, 2007 U.S. Dist. LEXIS 17347, at *54-*55 (D.N.J. Mar. 13, 2007) (finding scienter where plaintiffs alleged "a long list of difficulties [] encountered during the class period, which were either brought to the individual defendants' attention or such that persons in their positions would have been aware of them").

Vancocin accounted for over 50% of the Company's revenue, with an enormous 97 % profit margin. ¶ 156. It was a core drug and revenue driver for the Company. *Id.* Securing exclusivity for this important drug was extremely important to the Company. ¶¶ 38-43. It would be incredible to suggest that Defendants were not aware of details surrounding the sNDA application and approval as well as the Company's bid for exclusivity, including the information provided by the FDA at issue. *Vicuron*, CIV. A. 04-2627, 2005 WL 2989674, at *8 (finding inference of scienter where alleged misrepresentations related to company's leading drug product).

D. The Complaint's Confidential Sources Support Scienter

A plaintiff may rely on confidential sources to plead facts supporting scienter where the nature of their employment suggests that they were in a position to have access to the information they provided. *See, e.g., Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 146-48 (3d Cir. 2004) ("*Chubb*") (confidential sources meet the particularity requirements of Rule 9(b) and the PSLRA when "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged"). In evaluating such allegations, courts in the Third Circuit consider "the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *Avaya*, 564 F.3d at 263 (internal quotation marks omitted). Plaintiff meets that standard here.

Defendants' attacks on Plaintiff's confidential sources are without merit and contradicted by the law. CWs 1, 2, 4, 5 state collectively that Defendants were actively involved in the sNDA application and approval process—a fact that Defendants don't deny. That some of these confidential sources did not work at the Company during the Class Period is irrelevant. Def. Br. at 35. *See Astea*, 2007 WL 2306586, at *16 (holding that facts supporting an inference of scienter need not always be contemporaneous with the alleged misstatements). The sNDA application was filed in 2010 and the bulk of the FDA communications which form the basis of Plaintiff's Complaint occurred in 2011 during the time in which these CWs were employed at the Company. Thus given their positions and tenure at the Company, CWs 2, 4 and 5 would have been in a position to know what was going on in the Company during the time ViroPharma was communicating with the FDA regarding the sNDA approval. In addition, CW 2 discussed the Company's goal for conducting pediatric studies in order to qualify for exclusivity. CW 5 described meetings that Defendants Doyle, Wolf and other top executives attended where the significance of pediatric testing was discussed. These CWs support that Defendants knew the implications of PREA. ¶ 150. Even though CW 6 did not work at the Company, he was the scientist that designed the Genzyme Study, and is clearly relevant to the case. CW 6 supports what the FDA told Defendants—that the primary purpose of the Genzyme Study was to test tolevemar's efficacy, ***not*** Vancocin's. Contrary to Defendants' assertion, Plaintiff does not need to draw a "connection between him and any Defendant." Def. Br. at 34. *See e.g., Local 731 I.B. of T. Excavators and Pavers Pension Trust Fund v. Swanson*, No. 09-799, 2011 WL 2444675, at *4 (D. Del. June 14, 2011) (concluding confidential witness allegations supported strong inference of scienter despite defendants' efforts to "discredit witnesses who [] had no contact with Defendants"). Finally, Defendants question how "the sales staff" would have any knowledge about regulatory exclusivity. First, Defendants minimize these CWs positions. CW1 was the Manager of Sales Operations. CW 3 was a Senior Area Director in charge of Vancocin Sales. Both these individuals reported to the VP of Sales. CW2 was the Associate Director of Clinical Development and reported to the VP of Clinical Development. These were high ranking individuals at the Company. Moreover, as alleged in the Complaint, maintaining Vancocin's exclusivity was of utmost importance to the Company. ¶¶ 38-43. It stands to reason that these high ranking individuals would have been aware of the details surrounding Vancocin's exclusivity bid.

Thus, the CW allegations, when considered with Plaintiff's other well pled allegations, support a strong inference of scienter.

E. Defendants' Insider Trading Raises a Strong Inference of Scienter

1. The Trades Were Unusual in Scope and Timing

Allegations that stock sales were "unusual in scope or timing" adequately pleads motive in the Third Circuit and will raise a strong inference of scienter if, when viewed with the other allegations in the complaint, a reasonable person would deem the inference of scienter at least as compelling as any opposing inference. *Tellabs*, 551 U.S. at 325; *Suprema*, 438 F.3d at 277. "Whether a sale is 'unusual in scope' depends on factors such as 'the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved.' Other factors relevant include whether the sales were 'normal and routine,' and whether the profits were substantial relative to the seller's ordinary compensation." *Id.* The coordinated nature of insider sales are also relevant to motive and scienter. *See, e.g., In re Daou Sys. Inc. Sec. Litig.*, 411 F.3d 1006, 1024 (9th Cir. 2005), *cert. denied*, 546 U.S. 1172 (2006).

Defendants Doyle and Rowland's unusual insider trading raises a strong inference of scienter as to these Defendants and the Company. Defendants do not dispute the suspicious nature of the timing and volume of these sales. Nor can they. Doyle and Rowland sold their personal shares of ViroPharma stock for an aggregate total exceeding $8 million in profit over a four-month period.[19] ¶¶ 160-162. Their sales were obviously timed to coincide with the inflation caused by their material omissions; they dumped their shares just weeks before the FDA issued its response on the issue of exclusivity. ¶ 165.

These Defendants' Class Period sales were also extremely disproportionate to their pre-Class Period sales. For the entire year prior to the Class Period, Doyle and Rowland's stock sales totaled $405,400 compared to nearly $8 million during the four month Class Period. ¶ 164. The benefit they obtained is also grossly disproportionate to their compensation. ¶ 165. These insider trades provides an inference of scienter, a conclusion that is consistent with even Defendants' cited authorities. Def. Br. at 37-38; *see Avaya*, 564 F.3d at 279 ("if the stock sales were unusual in scope or timing, they may support an inference of scienter"); *In re Cybershop.com Sec. Litig.*, 189 F. Supp. 2d 214, 234-35 (D.N.J. 2002) (case featuring insider sales that were not suspiciously timed and "affected only minimally [defendants'] overall holdings."). Defendants Milano and Wolf's decision not to trade on material, non-public information does not negate the strong inference arising from the other Defendants' trades. *See, e.g.*, *Suprema*, 438 F.3d at 264, 277-78 (two defendants' insider sales for total proceeds of $7 million supported strong inference of scienter, notwithstanding four other defendants were not alleged to have engaged in insider trading); *Local 731*, 2011 WL 2444675, at *12 (D. Del. June 14, 2011) (listing "the number of insiders involved" as just one of the factors considered by the Third Circuit when analyzing insider sales).

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[19] *See*, *e.g.*, *Suprema*, 438 F.3d at 277 (two defendants' sales for total proceeds of $7 million supported strong inference of scienter); *U.S. Interactive*, 2002 WL 1971252, at *1 (strong inference of scienter alleged where three insiders sold 244,500 shares for less than $4 million in days following allegedly misleading public interviews)

2. ViroPharma's Repurchase Program Does Not Negate the Strong Inference of Scienter

The alleged share repurchase program does not negate the strong inference of scienter for several reasons. The Company's buying of its own stock could have augmented market demand, making it easier for Doyle and Rowland to make sales without depressing prices. *See No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holdings Corp.*, 320 F.3d 920, 928-30 (9th Cir. 2003) (strong inference of scienter plead where company repurchased nearly $100 million in its own stock during the class period); *In re Countrywide Fin. Corp. Sec. Litig.*, 588 F. Supp. 2d 1132, 1187 (C.D. Cal. 2008). In addition, the repurchase pattern is also consistent with Defendants' knowledge that the stock price was inflated. Despite authorizing management to repurchase $200 million in shares the Company repurchased only $50 million in shares during the Class Period (roughly 25% of the program's actual target). Def. Ex. 15 at 47.[20] In any event where, as here, Plaintiff has adequately pled conscious misbehavior or recklessness, the Court need not consider Defendants' argument that the stock repurchase plan negates scienter. *Plumbers & Pipefitters Local Union No. 630 Pension-Annuity Trust Fund v. Arbitron Inc.*, 741 F. Supp. 2d 474, 489, 491 n.5 (S.D.N.Y. 2010).

F. When Viewed Holistically, Plaintiff's Allegations of Scienter Are Compelling

Defendants' motion sets out to scrutinize each of Plaintiff's allegations in isolation, and argue that each, standing alone, is inadequate to raise a strong inference. However, this is not the standard under *Tellabs* which requires the Court to look at the scienter allegations holistically. *Tellabs,* 551 U.S. at 322-24.

Without a basis to attack Plaintiff's well-pled scienter allegations based on conscious misbehavior and/or recklessness, Defendants argue that Plaintiff's theory of scienter is irrational because Plaintiff does not explain what motive Defendants would have to lie to the market. Def. Br. at 36. Plaintiff ***does,*** however, allege a financial motive as to Doyle, Rowland and the Company.[21] Plaintiff also alleges that ***all*** Defendants engaged in a multi-year campaign to delay the introduction of generics, including improperly using the Citizen's Petition process—a finding that the FDA supports. ¶ 136. It is not implausible to suggest, as Plaintiff does, that the Defendants wanted to squeeze every last penny out of Vancocin by using the Citizen's Petition Supplement to delay introduction of generics - even if that meant only four to six more months of exclusivity while the FDA made its decision. ¶ 154.[22] In addition, the Company could have been trying to buy more time in the hopes that another statutory loophole could save the day.

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[20] The cases relied upon by Defendants here are at odds with the facts of this case. For example, in *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551 (E.D. Pa. 2009) (Def. Br. at 38), all of the defendant directors and officers "not only held onto their shares of *Adolor* stock during the Class Period, they actually increased their holdings incrementally throughout the Class Period." *Id.* at 572. Here, none of the Individual Defendants are alleged to have increased their holdings during the Class Period. Instead, Doyle and Roland sold stock for a significant amount during the Class Period (with Rowland selling nearly half of his holdings during the Class Period). ¶ 160. *Plumbers & Pipefitters Local Union v. Zimmer*, 673 F. Supp. 2d 718 (S.D. Ind. 2009) is also distinct because in that case (unlike here) there was "a lack of an allegation or evidence showing Defendants' access to or actual knowledge of material information." *Id.* at 748.

[21] Indicative of scienter is the fact that the Citizen's Petition Supplement caused a delay that allowed the Company to net Vancocin sales of $66 million, nearly half of the Company's quarterly new product sales, while the Company awaited a decision from the FDA. ¶ 154.

Regardless, Plaintiff does not need to establish motive to show scienter, where, as here, Plaintiff has shown "conscious misbehavior or recklessness." *In re Bristol-Myers Squibb Sec. Litig.*, No. CIV. A. 00-1990(SRC), 2005 WL 2007004, at *27 (D.N.J. Aug. 17, 2005) ("where a plaintiff can produce adequate evidence of scienter by demonstrating conscious misbehavior or recklessness, the question of 'motive' is irrelevant.").

Plaintiff's allegations, as described above, more than suffice to show that Defendants acted with the requisite scienter. Plaintiff's allegations accepted as true and considered ***collectively*** raise an inference of scienter that is at least as strong as any opposing inference defendants have suggested. *Tellabs*, 551 U.S. at 322-24.

IV. The Complaint Sufficiently Alleges a Section 20(a) Violation

The Complaint establishes underlying securities fraud violations against the Company, and thus, also establishes a control person claim against each of the Individual Defendants, who controlled the Company during the Class Period. ¶¶ 189-195. *Winer Family Trust v. Queen*,

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[22] Contrary to Defendants assertion, the Citizen Petition did delay the entrance of generics into the market. (Def. Br. at 5 n. 3). "Until 2007, the FDA was required to consider and respond to every citizen petition. For this reason, filing a citizen petition necessarily delayed the approval of any pending ANDA—***only after the FDA responded to all pending citizen petitions could an ANDA be approved***. The citizen petition process often was abused by pharmaceutical companies attempting to prolong their monopoly in the market." (emphasis added) *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 211 (E.D. Pa. 2012). In 2007, Congress passed 21 U.S.C. § 355(q) (also known as 505q) to remedy abuse of the Citizen Petition process, requiring the FDA to consider generic applications notwithstanding pending Citizen's Petitions. However, 505(q) does not apply to Defendants' Citizen's Petition because it was filed in 2006. *See* Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act at 5. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079353.pdf

CIV. A. 03-4318, 2004 WL 2203709 (E.D. Pa. Sept. 27, 2004), *aff'd*, 503 F.3d 319 (3d Cir. 2007) (Padova, J.) (finding control person allegations similar to those pled here sufficient to plead Section 20(a) claim).

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied. In the alternative, should the Court grant any part of Defendants' motion, Plaintiff requests leave to amend the Complaint.

Dated: New York, New York
February 4, 2013

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